UNICORN™ 7 software

CONTROL SOFTWARE FOR INDUSTRIAL SYSTEMS

Our UNICORN™ 7 software offers system control for chromatography, bioreactor, and filtration systems (Fig 1), providing built-in knowledge for planning and controlling runs, as well as analyzing results. With scalability in mind the software has been designed for use in small-scale bench-top systems, for research and process development applications, all the way up to full-scale GMP manufacturing processes. Retaining the advantages of previous versions, since its inception 30 years ago, this software has evolved with the advancement of technology and implementation of user-requested features.

Key benefits include:

- Ease-of-use through an intuitive user interface and fully interactive process layout for specific systems.
- Data security provided by robust database handling and user security levels.
- Regulatory support including validation support files, qualification support, good automated manufacturing practice (GAMP 5) support, and compliance with 21 CFR Part 11.
- Flexible software features allowing operators to make adjustments without the need of an automation engineer.
- Efficiency of time and resources through remote access capabilities and secure sharing of data.
- Interactive process picture available for specific systems.

Description

UNICORN 7 software is based on an integrated controller and an intuitive computer-based interface. To minimize the learning curve, the interface uses a familiar Windows® environment. With a graphical interface to help you, a run sequence is fully determined by the end user for maximum control of the process. Advanced users can perform conventional line programming.

UNICORN 7 software contains the tools needed to perform a wide range of applications, such as protein purification, filtration, and cell culture at different scales, from setting up and running a method to evaluating the data. The software uses instrument configurations that contain all instructions, macros and component descriptions needed to operate each specific system.

Fig 1. UNICORN 7 software allows manual and automated control of process systems

The software has four modules:

Administration: used to set up each system with its installed components, user access, view logs, and management of the inbuilt SQL Server database.

System Control: allows you to perform and monitor the run in real time.

Method Editor (Recipe Editor): provides an easy interface to help you create or modify methods.

Evaluation: supports data analysis and report generation. Additional tools for data handling and reporting are available in the optional Evaluation classic module.

Integrated tools such as ***Column Handling*** extend across the different modules, helping to increase productivity.

UNICORN online and ***My Instruments*** are web apps that support control and monitoring of runs when you need to be away from the equipment. Remote monitoring can also be done with a remote UNICORN client.

Administration module

The **Administration** module shows the system logs and properties. It also gives you control of database management and user setup. Data is stored in a SQL Server database (UNICORN software 6.0 or higher), which provides secure and robust data storage where data can be easily accessed, archived, and searched. Depending on the number of users and integrated systems simultaneously accessing the same database, SQL Server Express (included for standalone installations) or full Microsoft® SQL Server (for networked installation, sold separately from Microsoft) is suggested for optimal operation.

Administration features include:

- User management, including creation of users, password management, and user access (LDAP authentication supported).
- System management, including define instrument, manage configuration and properties.
- Ability to view, print and export UNICORN 7 software system log (audit trail).
- Database management such as ***Archive/Retrieve*** and ***Backup/Restore*** scheduling (only applicable for SQL Express as part of the UNICORN installation). For centralized SQL installations, these functions are handled by the customer's Database Administrator.
- Management of automated system messages through email notifications e.g., when an alarm or error occurs during a run.

System control module

The **System Control** module is a powerful environment for process operation. As an operator you can initiate a phase/operation, manually interact with the system, and monitor the status of the system. Operators can also adjust a running process in real time, as allowed by applicable user permissions (Table 1).

The **System Control** module has customizable panes showing the process data curves, current sensor values, process event log, and process picture (graphic). As an operator you have the flexibility to choose which panes are displayed, and tailor the layout to suit your specific needs (Fig 2).

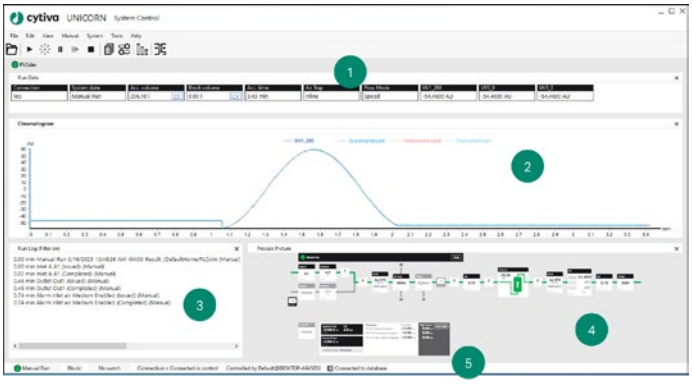
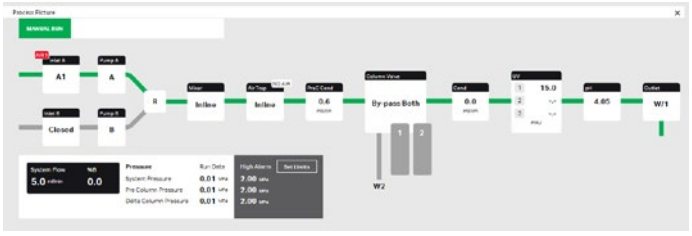


Fig 2. The **System control** module uses dockable panes to display parameters such as current run data values for each sensor (1), chromatogram curves (2), run log (3), and interactive process picture with the current flow path (4). At the bottom, the status bar (5) indicates the instrument and database connection. These panes can be viewed full screen or customized to the viewer's preference. Run data and chromatogram curves can be hidden or viewed in each window to customize the view.

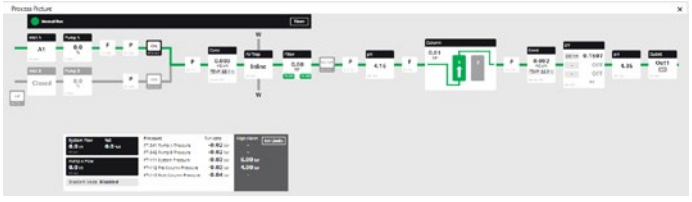
Full control is available when operating a UNICORN 7 controlled system. System components and process parameters can be changed at any time (subject to applicable user permissions) and all interactions and events are captured in the event log and historized.

The software features a real-time process picture showing the current flow path, valve positions, sensor values, and quick access to often used parameters like pressure alarms, pump control, etc. (Fig 3).

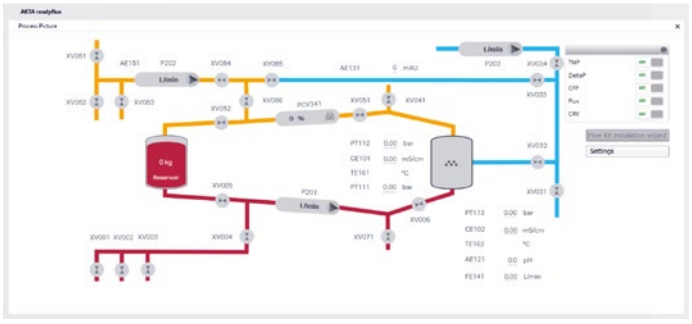
(A)



(B)



(C)



(D)

Fig 3. Examples of the interactive process picture in UNICORN 7 software from (A) ÄKTA pilot™ 600 chromatography system; (B) ÄKTA process™ chromatography system; (C) ÄKTA readyflux™ tangential flow filtration system and (D) ReadyToProcess WAVE™ 25 rocking bioreactor.

Method Editor (Recipe Editor) module

The **Method Editor** module of UNICORN 7 software allows you to create or adjust operations to suit your application or process needs. It contains all the equipment operations to build phases and subsequently entire operations (methods), see Table 1. The interface provides easy viewing and editing of all operational layers.

Table 1. Terms defined for Method Editor module

Industry standard ISA-88 (1)	UNICORN software	Description
Unit procedure	Method queue	An ordered set of operations. Describes a set of operations that will carry out a process stage.
Operation	Method	An ordered set of phases. An operation combined with a unit is a process operation.
Phase	Phase	The lowest level in the procedural control model.
Equipment operation	Instruction	An operation that is part of equipment control.

Methods (operations) are built using phases. Each phase reflects a step in the operation, such as ***Sample Application*** or ***Column Wash***. Phases consist of a sequence of equipment operations (instructions). Once created you have the option to save phases in the ***Phase Library***, a feature that provides efficiency when writing phases in the future.

Methods (operations) can be created or edited by dragging-and-dropping phases from the ***Phase Library*** into the ***Method Outline*** and setting important parameters in the ***Phase Properties*** pane (Fig 4).

Alternately the ***Text Editor*** allows building line-by-line instructions for each individual component of the system. Users (as defined in the **Administration** module) can build logical phases or entire unit procedures at the text level.

In addition to building stand-alone methods (operations), for example, the capture step of a three-step chromatography process, **Method Editor** can assemble multiple methods (operations) into a ***Unit Procedure***. This is called ***Method Queue***.

Evaluation module

The UNICORN 7 historian is fully integrated with built-in chromatography and filtration-specific analysis and reporting tools within the **Evaluation module** of the software. This module provides a simplified user interface optimized for commonly used workflows like quick evaluation, comparison of results, and work with peaks and fractions. The evaluation module is optimized for chromatography but can also be used to view results from other application areas such as cell culture and filtration operations. Evaluation features for chromatography systems include:

- Column qualification run analysis (e.g., HETP*, asymmetry, and transitional analysis).
- Simplified interface, including single-click operations with instant feedback for operations like peak integration and shift offset.
- Preview of results for quick evaluation.
- Comparison of results in column volumes (CV) for scale-up/down.
- Comparison of results in overlay and tile view. Sort results according to running parameters to see trends in data (Fig 5A).
- Auto peak integration.
- Amount and concentration calculation in peaks (Fig 5B).
- Possibility to align peaks to fractions.
- Possibility to normalize UV data generated with UV cells of different path lengths (UNICORN v7.1 or higher).

* Height equivalent to a theoretical plate.

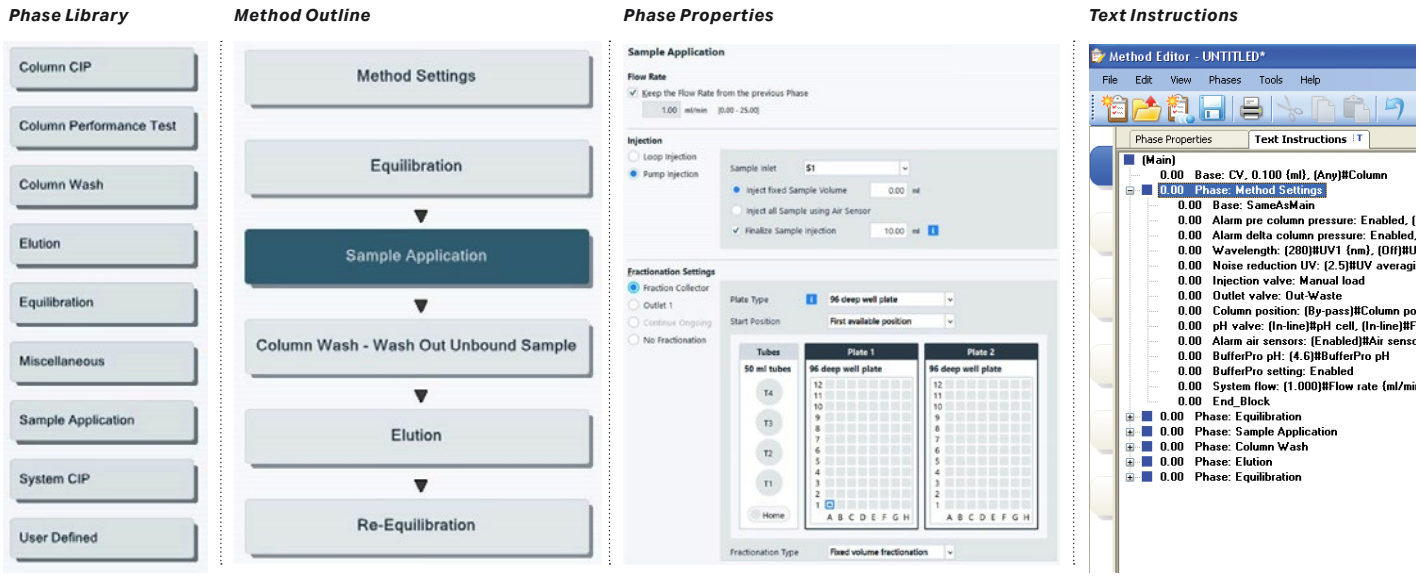
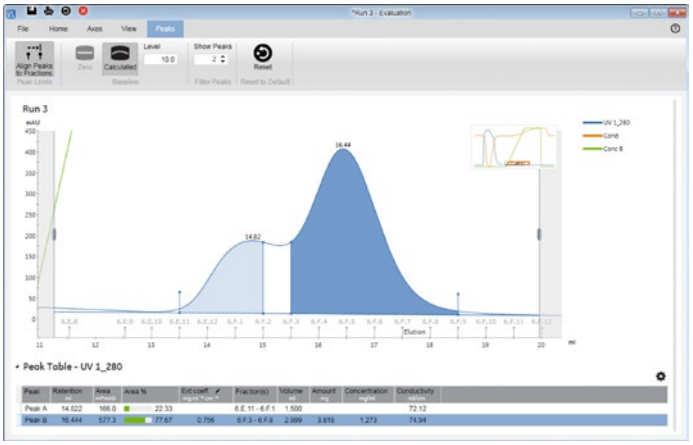


Fig 4. The different parts of the **Method Editor**.

(A)



(B)

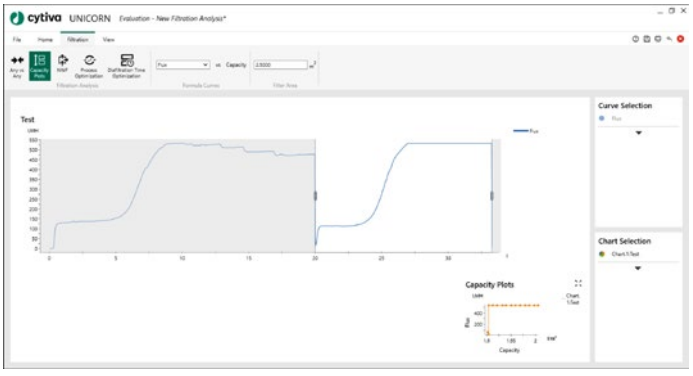


Fig 5. Two different views from the **Evaluation** module (A) peak area calculation of protein amount and concentration; (B) filtration capacity plot.

SQL database

UNICORN 7 software stores all system configurations and process data in an SQL-based database with a flexible architecture, supporting both centralized and decentralized deployment options. This approach enables local and remote access to **historical data**. Additionally, the software can communicate with external historians used by various distributed control systems (DCS) through an Open Platform Communications Universal Architecture server (OPC-UA server), enabling **historical process data** to be stored in a new or existing onsite data repository.

Note: For real-time data, the OPC-UA server interfaces directly with the UNICORN Instrument Server.

For more detailed information, see the UNICORN Administration and Technical Manual.

Filtration applications

UNICORN software supports ultrafiltration and microfiltration applications as well as filter cleaning and storage using ÄKTA readyflux tangential flow filtration system. The interactive process picture is color-coded (Fig 3) showing retentate, permeate and feed sections of the flow path. Predefined method templates and predefined phases allow you to create or adjust methods to suit your application needs. In System control, the user has automated feedback control of the filtration process (e.g., TMP, delta pressure, flux and constant retentate volume), end-point monitoring on multiple parameters and automated maintenance alerts.

The **Evaluation** module includes several workflows to support filtration applications:

- Capacity plots such as flux vs capacity, transmembrane pressure (TMP) vs capacity, and external vs capacity (v7.2 or higher).
- Diafiltration time optimization (v7.2 or higher).
- Process optimization and overlay of multiple plots (v7.2 or higher).
- Any two process parameters captured during a filtration run (v7.1 or higher) can be plotted graphically.
- Normalized water flux (NWF) to test membrane permeability.

For more details, see the data file for ÄKTA readyflux system or other supported filtration systems.

Interface with historians and manufacturing facilities

Systems controlled with UNICORN 7 control software can be used in manufacturing facilities with third-party historians through several interface options such as Profibus, OPC-UA, and I/O. This allows for data to be captured both within UNICORN 7 software and sent externally to the desired historian simultaneously.

Supported systems

UNICORN 7 software supports a range of our systems. For more details on how the software works with each system, see the specific data files listed in Table 2.

Table 2. Systems supported by UNICORN control software

Technique	System	Document	Document number
Large-scale chromatography	ÄKTA process system	Data file	CY28632
Single-use chromatography	ÄKTA ready™ 450 system ÄKTA ready system ÄKTA ready XL system	Data file Data file Data file	CY23111 CY10671 CY13866
Continuous chromatography	ÄKTA pcc™ system BioProcess pcc	Data file N/A	CY15729 N/A
Single-use tangential flow filtration	ÄKTA readyflux system ÄKTA readyflux XL system	Data file Data file	CY13924 CY9185
Rocking bioreactor	ReadyToProcess WAVE 25 bioreactor	Data file	CY11757
Pilot-scale chromatography	ÄKTA pilot 600 system	Data file	CY11723
Inline conditioning	BioProcess™ IC system	Data file	CY11780
Lab-scale chromatography	See the separate UNICORN software data file for bench-scale chromatography systems	Data file	CY12681
Oligonucleotide synthesis	ÄKTA oligosynt™ synthesizer OligoPilot™ synthesizer OligoProcess™ synthesizer	Data file N/A N/A	CY26389 N/A N/A
Cell therapy	Xuri™ W25 cell expansion system	Data file	CY11894

Integrated tools in UNICORN 7 software

UNICORN 7 software includes several integrated tools and extensions for managing bioprocess applications.

Process control tools

The ***Watch*** function enables you to control processes with regards to monitor signals. In a ***Watch*** instruction, an action specified by the user is executed if a certain condition is met. For example, a ***Watch*** instruction can terminate column equilibration earlier if the eluent conductivity reaches a certain value defined by the user. The ***Watch*** instruction can be used for various purposes such as improving accuracy of collection, improving robustness of a chromatographic step, ending a concentration step, stopping the media feed in a bioreactor (saving time and material), and automating entire runs.

Column handling and logbook

To increase operational safety and column reproducibility, UNICORN 7 software offers ***Column Handling*** and ***Column Logbook*** as optional features.

Column Handling saves column specifications to a library. When building methods (operations) the columns can be selected from the library, and subsequently important column parameters such as, but not limited to, maximum pressure, default flow, maximum flow, column volume (CV), bed height, and column diameter will be saved as part of the operation. This ensures proper specifications are carried with the column whenever it is incorporated into an operation.

Column Logbook provides traceability by keeping track of important column and run data. It captures and documents the entire lifecycle of a given column.

This information can be used in production environments in several important ways:

- Production lot traceability.
- Column maintenance tracking.
- Column cleaning traceability.
- Column qualification, requalification triggering, and documentation.

Column History collates all column run data.

Process-scale column support

Intelligent Packing is included with UNICORN 7 software running ÄKTA process and ÄKTA pilot 600 chromatography systems. The software automates the packing and unpacking of AxiChrom™ pilot-scale chromatography columns (50 to 200 mm diameter) to deliver consistent and reproducible well-packed columns. Our validated methods and simple user-defined inputs such as resin type, slurry concentration, and target bed height, enhance its usability.

The AxiChrom column controller is incorporated for process-scale columns of 300 mm diameter and higher. ***Intelligent Packing*** is integral to operation of the control unit and can interface with and be controlled by UNICORN 7 software. The same simple user inputs are all that is required to pack and unpack these larger columns.

UNICORN 7 software also supports ReadyToProcess™ prepacked validated chromatography columns.

Inline conditioning for automated buffer preparation

The BioProcess IC System is a buffer management system for inline buffer preparation using concentrated single component stock solutions of acid, base, salt, and water for injection (WFI). The use of concentrates significantly reduce buffer volumes, saving both floor space and tank volumes. The ***Buffer Verification Function*** (BVF) in the UNICORN 7 software can monitor the pH and conductivity of the mixed buffer in real time. For more details, see the BioProcess IC System data file (CY11780).

UNICORN 7 software extensions

Extensions are software plug-ins that add capabilities to your UNICORN 7 software. They are managed from the **Administration** module. Some examples of these extensions are listed here:

- Dynamic Binding Capacity (DBC) calculations.
- UNICORN software trending tool: enables quick comparison of key parameters from high throughput rapid cycling of column chromatography data.
- UNICORN 5 Import Extension: enables bulk import of UNICORN 5 software results and methods while preserving folder structures.

Download extensions at Cytiva.com/marketplace. Find the software trending tool on the UNICORN software product page.

Note: The Marketplace can include both officially released and beta-release extensions. Support may be limited for some extensions. See the Cytiva Marketplace for currently available extensions.

Companion tools

My Instruments

My Instruments offers a real-time dashboard of your entire fleet of systems. At a glance, you can view the status of specific systems, process variables, curves, and any alarms that may need attention (Fig 6). You can simply click to see additional system information like logged-in users and running method status. ***My Instruments*** provide historical utilization data such as runtime, idle time and the amount of time the system is offline.

My Instruments can display systems controlled by UNICORN 7.6 or higher. You can access this tool in a web browser without installing any applications.

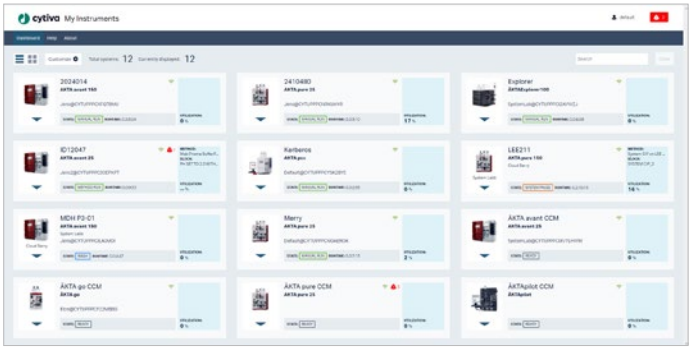


Fig 6. ***My Instruments*** offers a real-time overview of your systems.

UNICORN online

UNICORN online provides intuitive real-time control and monitoring of your system, and lets you easily view results from any mobile device (Fig 7) or remote computer. For example, with ***UNICORN online***, you can adjust a run parameter while sitting in a conference room.

You can access ***UNICORN online*** from a web browser without installing any applications. The app supports research-scale systems as well as ÄKTA pilot 600 systems.

Fig 7. Control, monitor, and view results on your phone with the ***UNICORN online*** app.

Regulatory support

We have more than two decades of experience in developing regulatory-compliant software and have taken many steps to support good-x-practice (GxP) to comply with regulatory requirements, utilizing procedures and documentation that comply with standards accepted throughout the biopharmaceutical industry. UNICORN software is present in many registered and approved manufacturing processes.

UNICORN software products support a current good manufacturing practice (cGMP)-regulated environment and help maintain electronic records. All data (e.g., results and extensive run documentation records), events, and configurations are stored in a single, unalterable database, in line with GAMP 5 and related good practice guides. The software offers functionality that helps manufacturers meet US Food and Drug Administration (FDA) 21 CFR Part 11 and EU GMP Annex 11 regulatory guidelines, including a system audit trail, electronic signatures, and electronic records (2, 3).

Validation support is accessible through our Regulatory Support page. After registration, you have access to comprehensive documentation on control system validation, installation qualification (IQ), and operational qualification (OQ) services.

Available support documentation includes:

- Detailed description of the development model used for UNICORN 7 software.
- 21 CFR Part 11 system assessment in checklist format.
- Self-Assessment Questionnaire (SAQ) provided in the Validation Support File (VSF).

Visit Cytiva.com/rsf to register for change control notifications and access to validation guides and regulatory support files.

Integration and remote capabilities

UNICORN 7 software can be deployed in several different ways, to allow availability of functionality in a networked configuration (Fig 8).

Advantages of network setup include data sharing, remote control and a centralized administration. Floating licenses are also available for optimized usage.

OPC protocols

UNICORN OPC-UA server provides a standardized integration interface to support integration between UNICORN and other software systems such as Laboratory Information Systems (LIMS) and Manufacturing Execution Systems (MES or SCADA). OPC-UA enables open connectivity via open standards created in collaboration with leading automation manufacturers worldwide, including Microsoft®. OPC-UA provides inter-operability between system components by creating and maintaining open standard specifications.

- UNICORN OPC data access server (DA server) gives access to all process data.
- UNICORN Alarms and Events server (AE server) informs an OPC client that a system parameter has exceeded an upper or lower limit value.
- UNCORN historical data access (HDA) allows any OPC client application to access the batch result generated by UNICORN software.
- UNICORN OPC Security controls client access to the above data, while protecting sensitive information and guarding against unauthorized modification of process parameters.

OPC-UA = Open Platform Communication Unified Architecture
SCADA = Supervisory control and data acquisition.

For more information, see the UNICORN OPC manual.

Privacy and security

UNICORN 7 software has been designed with a broad assortment of capabilities to enable privacy and security protection, adhering to ISA-95 enterprise-control system integration and auditing through compliance with 21 CFR Part 11. These capabilities include:

- Access controls.
- Privacy and security audit logging and accountability controls.
- Information protection.
- Protection from malicious attacks (the use and configuration of firewall and antivirus software is encouraged).
- Data integrity capabilities.

For more details, see the UNICORN Privacy and Security Manual for your specific version of the software.

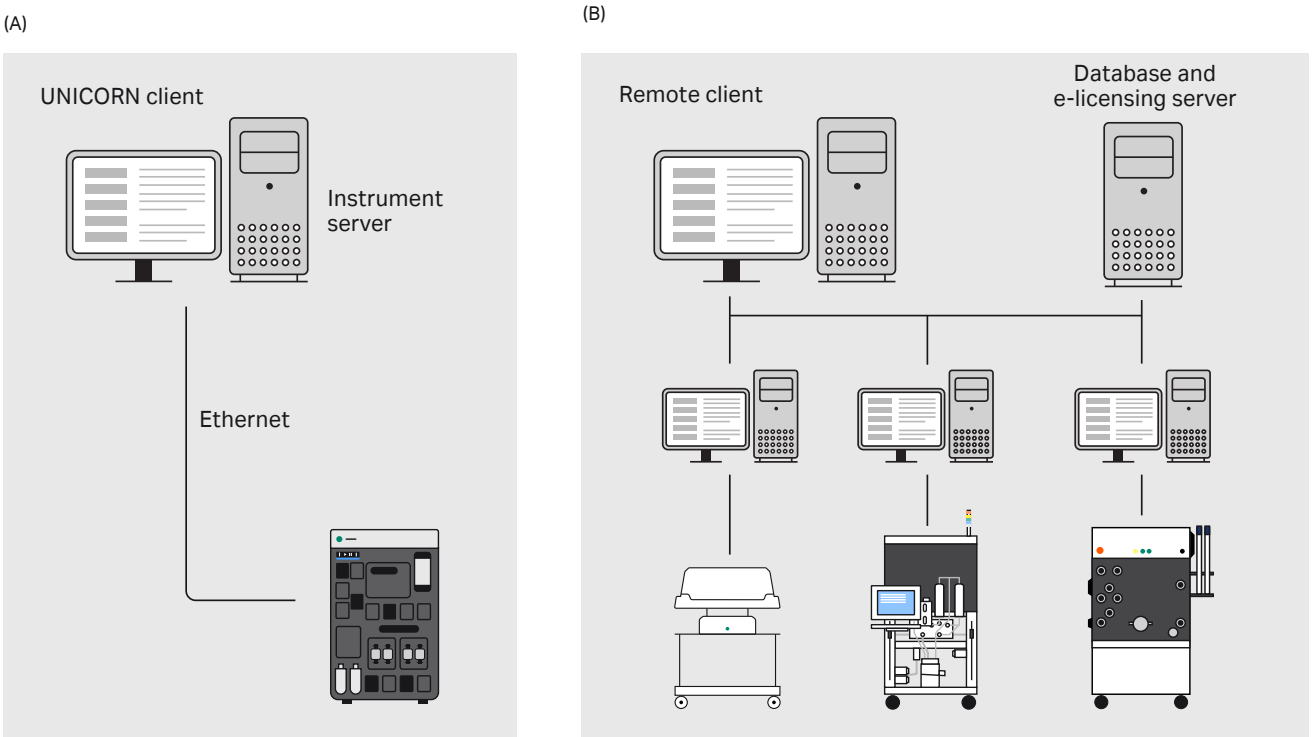


Fig 8. (A) Each manufacturing-scale system is controlled by a dedicated instrument server; (B) In a network with multiple instruments, each system is connected to its own instrument server and an additional server is used as the database and e-licensing server.

Services and support

OptiRun™ services

Our service team can provide a range of services for your equipment including validation support, preventative maintenance and repairs utilizing run log data and any error reports in UNICORN 7 software.

More information can be found at cytiva.com/optirun.

Training

Several types of training courses, both classroom and self-directed are also available (Table 3).

Additional classroom and self-directed courses for hardware products also include training related to UNICORN control software. See the complete catalog at cytiva.com/OnlineLearning.

Several tutorial videos for the Evaluation module are available on this YouTube playlist.

Requirements

Operating system: Windows

Database: UNICORN software includes SQL Server Express 2022. This can support up to three systems in a networked environment. For more than three systems, performance improvements are seen with SQL Server Standard, SQL Server Enterprise, or SQL Data Warehouse (available separately from Microsoft).

Contact your local Cytiva representative for full technical specifications.

UNICORN 7 software is tested using an English operating system. Using other language versions may cause errors.

Table 3. Training and learning courses that include UNICORN control software

Course name	Type	Cost	Learn more
Get started: UNICORN for chromatography	E-learning	Free	cytivalifesciences.com/training/training-catalog/object/course-2309571
Get confident: UNICORN method editing for chromatography	E-learning	Free	cytivalifesciences.com/training/training-catalog/object/course-4146139
Advanced UNICORN system control for chromatography systems (UNI1)	Fast Trak™ classroom	Paid	cytivalifesciences.com/training/training-catalog/object/course-6547525
Advanced UNICORN system control for chromatography systems (vUNI1)	Fast Trak virtual	Paid	cytivalifesciences.com/en/us/training/training-catalog/object/course-6745769
Advanced UNICORN method editing for cell therapy (UNI2)	Fast Trak classroom	Paid	cytivalifesciences.com/training/training-catalog/object/course-4531129

Table 4. Supporting documentation to aid Windows installation for UNICORN software

Document name	Document article number	What's included
Computer specifications	29283583	Minimum computer specifications for the UNICORN client and database server.
UNICORN compatibility matrix	29258394	Describes operating systems, SQL database versions, and instruments supported by each 6.x and 7.x release.
Software change description	29293765	Describes what has changed in each 6.x and 7.x release and any impact on Windows setup.

Ordering information

Products	Code number
License packages (see the product web page for details)	
UNICORN 7 Process Development	29203854
UNICORN 7 Manufacturing	29203855
UNICORN 7 package for Filtration/WAVE	29708936
Workstation license for all systems	
UNICORN 7 WrkStn pure-BP-exp	29128116
Optional licenses	
UNICORN 7 Remote	29115426
UNICORN 7 Dry	29115427
UNICORN 7 Column logbook lic	29115441
UNICORN 7 StdAlon Evaluation	29115454
UNICORN 7 Evaluation Classic	29115456
UNICORN 7 DVD pack no license	29128020
UNICORN 7 Manual package (Printed copies of UNICORN manuals)	29127795

Related information (hardware)	Reference
ÄKTA pilot 600 system	cytiva.com/aktapilot600
ÄKTA pcc and BioProcess pcc systems	cytiva.com/aktapcc
ÄKTA process CFG system	cytiva.com/aktaprocess
ÄKTA ready single-use chromatography system	cytiva.com/aktaready
ÄKTA ready XL single-use chromatography system	Web page
ÄKTA readyflux and ÄKTA readyflux XL systems	cytiva.com/aktareadyflux
AxiChrom columns	cytiva.com/axichrom
Buffer preparation (inline conditioning system)	Web page
Oligosynthesizers	Web page
ReadyToProcess WAVE 25 rocking bioreactor	cytiva.com/wave
UNICORN software for research-scale systems	cytiva.com/unicorn

Related information (software)	Reference
UNICORN software extensions	cytiva.com/marketplace
Compatibility matrix	See Documents* on cytiva.com/unicorn
Computer specifications	
Installation checklist	
Operation manuals for UNICORN software	
OPC manual	
Privacy and Security Manual	
Software Change Description for each v7 release	
Validation Support File for UNICORN software	cytiva.com/rsf
Automation and digital solutions	Web page

Related information – service and support	
Regulatory support	cytiva.com/rsf
My Instruments and UNICORN online	cytiva.com/unicorn

* Some documents are valid for all UNICORN versions and others are specific to each version.

References

1 International Society of Automation. ISA88: Batch control. www.isa.org/standards-and-publications/isa-standards/isa-standards-committees/isa88

2 EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines. https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

3 U.S. Food & Drug Administration. 21 CFR Part 11, Electronic Records; Electronic Signatures — Scope and Application. www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11

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